NOV 2 2 2011

K112647

Page 1-of-3

510(k) Summary

1. Submitter Information

Application Correspondent

Contact person	Teling Hsu
Address	3F, 5F, No.127, Wugong 2nd Rd., Wugu District, New Taipei City, 24888, Taiwan
Phone	(+886-2) 6625-8188 ext.1176
FAX	(+886-2) 6625-0288
E-mail	teling.hsu@taidoc.com.tw
Date Prepared	September 5, 2011

Applicant

Contact person	Brian Chong
Company Name	Wistron Corporation
Address	21F, No. 88, Sec.1, Hsin Tai Wu Rd., Hsichih, New Taipei City 221, Taiwan
Phone	(+886-2) 6612-1344
FAX	(+886-2) 6612-2384
E-mail	brian_chong@wistron.com

2. Name of Device

Trade/Proprietary Name	BestShape Blood Pressure Monitoring System
Common Names	Blood pressure test system
Product Code	DXN
Classification Panel	Cardiovascular
Regulations	Class II, 21 CFR 870.1130

3. Predicate Device

Trade/Proprietary Name:	CLEVER TD-3018A™ Blood Pressure Monitor
Common/Usual Name:	Blood pressure test system
Submitter	TaiDoc Technology Corporation
510 (k) Number	K051703

Page 1 of 3

4. Device Description

The BestShape Blood Pressure Monitoring System uses the oscillometric method to measure the systolic, diastolic blood pressure and pulse rate with an inflatable wrist cuff on adults.

5. Intended Use

The BestShape system is a system designed to measure blood pressure non-invasively. It is intended for use at home and in clinical settings. The measurement position of the device is the wrist of the subject. This system should be used for the testing on people over age of 18.

The device is not to be used for the diagnosis or screening of hypertension or for testing on newborns

6. Comparison to Predicate Device

The BestShape Blood Pressure Monitoring System and the predicate device both use the oscillometric method within the software algorithm to determine the systolic, diastolic blood pressure and pulse rate with an inflatable wrist cuff.

The major difference between the two devices is the physical appearance of device including outer casing design, printing and buttons. The minor software change has added the data transmission function with USB data port which connects the device and Personal Computer. User may use the compatible software program, the Health Care Software System (cleared under: K1109428), and review the test results on Personal Computer.

7. Performance Studies

The Best Shape Blood Pressure Monitoring System was validated by the tests according to IEC80601-2-30:2009 and met the requirements of ANSI/AAMI/ISO 81060-2:2009.

Software validation was performed to verify and validate the system works functionally.

Testing performed also included electrical safety, EMC and biocompatibility. The proposed device met the requirements of IEC/EN 60601-1 and IEC/EN 60601-1-2. The

K112647

materials of wrist cuff met the requirements of ISO 10993-5 and 10993-10.

8. Conclusion

The BestShape Blood Pressure Monitoring System demonstrates the safety and effectiveness for its intended use and it is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

NOV 2 2 2011

Wistron Corporation
c/o Mr. Teling Hsu
Regulatory Affairs Specialist
TaiDoc Technology Corporation
3F, 5F, No.127, Wugong 2nd Rd. Wugu District
New Taipei City
Taiwan, 24888

Re: K112647
Trade/Device Name: Bestshape blood pressure monitoring system (model TD-3028)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive blood pressure measurement system
Regulatory Class: Class II (two)
Product Code: DXN
Dated: September 5, 2011
Received: September 12, 2011

Dear Mr. Hsu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K112647

Device Name: BestShape Blood Pressure Monitoring System

Indications for Use:

The BestShape system is a system designed to measure blood pressure non-invasively. It is intended for use at home and in clinical settings. The measurement position of the device is the wrist of the subject. This system should be used for the testing on people over age of 18.

The device is not to be used for the diagnosis or screening of hypertension or for testing on newborns

Prescription Use _____ And/Or Over the Counter Use __X__.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off
Office of Device Evaluation (ODE)
510(k)_____

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K112647